

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Summary Minutes

Date: February 3, 2003

Place: Building 31, Conference Room 10  
National Institutes of Health  
Bethesda, Maryland 20892

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE  
NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

February 3, 2003

The 171<sup>st</sup> meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on February 3, 2003, at 8:35 a.m., in Building 31, Conference Room 10, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 8:35 a.m. to 11:20 a.m., followed by the closed session for Council business and consideration of grant applications from 12:30 p.m. until adjournment at 2:45 p.m. Dr. Lawrence A. Tabak presided as Chair.

Members Present:

Dr. John F. Alderete  
Dr. Louise T. Chow  
Dr. Nereyda P. Clark  
Dr. Samuel F. Dworkin  
Dr. Raymond J. Fonseca  
Dr. Jay Alan Gershen  
Dr. Howard K. Kuramitsu  
Dr. Francis L. Macrina  
Dr. Harold Morris  
Dr. Linda C. Niessen  
Dr. E. Dianne Rekow  
Dr. Martha J. Somerman  
Ms. Kim Smykil Uhrich

Members of the Public Present:

Mr. Jack Bresch, Associate Executive Director, American Dental Education Association (ADEA),  
Washington, DC  
Dr. Robert J. Collins, Deputy Executive Director, American Association for Dental Research,  
Alexandria, VA  
Ms. Terrie Cowley, President, The TMJ Association, Milwaukee, WI  
Ms. Gina Luke, Director, State Government Relations and Advocacy Outreach, ADEA,  
Washington, DC  
Ms. Monette McKinnon, Director, Grassroots Advocacy and State Issues, ADEA, Washington,  
DC  
Ms. Myla Moss, Director, Congressional Relations, ADEA, Washington, DC

Dr. Michael Reed, Dean, Dental School, University of Missouri, Kansas City, MO  
Mr. Jonathan Schuermann, Ph.D. Candidate, University of Missouri, Columbia, MO  
Ms. Ase I. Sewall, Senior Systems Analyst, Social & Scientific Systems, Silver Spring, MD  
Dr. Richard Weaver, Associate Director, Center for Educational Policy and Research, ADEA,  
Washington, DC

Federal Employees Present:

National Institute of Dental and Craniofacial Research:

Dr. Lawrence A. Tabak, Director, NIDCR  
Dr. Dushanka V. Kleinman, Deputy Director, NIDCR  
Dr. Margo Adesanya, Senior Scientist and Program Director, Clinical Trials and Patient-Oriented Research Program, Division of Population and Health Promotion Sciences (DPHPS)  
Ms. Carolyn Baum, Committee Management Specialist and Council Secretary, Office of the Director (OD)  
Ms. Carol M. Beasley, Chief, Human Resources Management Branch, Office of Administrative Management (OAM)  
Dr. Henning Birkedal-Hansen, Scientific Director, NIDCR, and Director, Division of Intramural Research (DIR)  
Ms. Amy Blackburn, Management Intern, OAM  
Dr. Norman S. Braveman, Assistant to the Director, OD  
Dr. Patricia S. Bryant, Health Scientist Administrator and Program Director, Behavioral and Social Sciences Research Program, DPHPS  
Ms. Sharrell S. Butler, Diversity Program Manager, OD  
Ms. María Teresa Canto, Health Scientist Administrator and Program Director, Population Studies Program, DPHPS  
Dr. Lois K. Cohen, Associate Director for International Health, NIDCR, and Director, Office of International Health (OIH)  
Mr. George J. Coy, Chief, Financial Management Branch, OAM  
Ms. Mary Daley, Grants Management Officer, Grants Management Branch (GMB), Division of Extramural Activities (DEA)  
Dr. Raymond Dionne, Chief, Pain and Neurosensory Mechanisms Branch, DIR  
Ms. Yvonne H. du Buy, Associate Director for Management, and Chief, OAM  
Dr. Caswell A. Evans, Director, National Oral Health Initiative, Office of the Surgeon General, and NIDCR  
Mr. William Foley, Grants Management Specialist, DEA  
Dr. Isabel Garcia, Special Assistant for Science Transfer, Office of Communications and Health Education (OCHE), OD, and Co-Director, Residency Program in Dental Public Health at NIDCR, DPHPS  
Ms. Christen Geiler, Computer Specialist, Office of Information Technology (OIT), OD  
Dr. Sharon Gordon, Special Assistant for Research Training, Career Development and Education, OD  
Dr. Kevin Hardwick, International Health Officer, OIH  
Dr. H. George Hausch, Acting Director, DEA  
Ms. Kathy Hayes, Dental Public Health Resident, HPAD, DPHPS

Dr. Alice Horowitz, Senior Scientist, DPHPS  
 Dr. Jeff Hyman, Epidemiologist, HPAD, DPHPS  
 Ms. Lorraine Jackson, Extramural Recruitment and Outreach Program Specialist, OD  
 Dr. Lynn King, Scientific Review Administrator, DEA  
 Ms. Sandra King, Program Assistant, OD  
 Dr. Albert Kingman, Chief, Biostatistics Core, DPHPS  
 Dr. Eleni Kousvelari, Chief, Cellular and Molecular Biology, Physiology, and Biotechnology Branch, Division of Basic and Translational Sciences (DBTS)  
 Dr. Wendy A. Liffers, Director, Office of Science Policy and Analysis (OSPA), OD  
 Dr. James A. Lipton, Special Assistant for Research, Infrastructure and Curriculum Development, OD  
 Dr. Jack London, Deputy Scientific Director, DIR  
 Dr. Dennis F. Mangan, Chief, Infectious Diseases and Immunity Branch, DBTS  
 Dr. J. Ricardo Martinez, Executive Secretary, NADCRC, and Associate Director for Program Development, OD  
 Ms. Rochelle Mendoza, Program Assistant, OD  
 Ms. Ellie Murcia, Program Analyst, OD  
 Ms. Yewande Morgan, Dental Public Health Resident, HPAD, DPHPS  
 Dr. Richard L. Mowery, Chief, Clinical, Epidemiology and Behavioral Research Branch, DPHPS  
 Mr. Christopher Myers, Lead Grants Management Specialist, GMB, DEA  
 Dr. Ruth Nowjack-Raymer, Health Scientist Administrator and Program Director, Health Disparities Research Program, DPHPS  
 Dr. Bruce L. Pihlstrom, Acting Director, DPHPS  
 Ms. Diana Rutberg, Grants Management Specialist, GMB, DEA  
 Dr. Ann L. Sandberg, Acting Director, DBTS  
 Dr. Jaya Satish, Health Scientist Administrator, Cellular and Molecular Biology, Physiology, and Biotechnology Branch, DBTS  
 Dr. Robert H. Selwitz, Chief, HPAD, and Director, Residency Program in Dental Public Health at NIDCR, DPHPS  
 Dr. Yasaman Shirazi, Health Scientist Administrator and Program Director, Epithelial Cell Regulation and Transformation Program, DBTS  
 Mr. Patrick Shirdon, Budget Analyst, OD  
 Dr. Rochelle Small, Health Scientist Administrator and Program Director, Developmental Biology and Mammalian Genetics Program, DBTS  
 Dr. Carolyn Tolbert, Program Analyst, OSPA, OD  
 Ms. Traci Walker, Committee Management Assistant, OD  
 Ms. Lynn Warwick, Executive Assistant to the Director, NIDCR  
 Mr. James Webb, Program Assistant, OD  
 Ms. Anne Welkener, Grants Management Specialist, GMB, DEA  
 Ms. Dolores A. Wells, Program Analyst, OSPA, OD  
 Ms. Mary Ann Williamson, Computer Specialist, OIT, OD

Other Federal Employees:

Dr. Fred Eichmiller, Director, Paffenbarger Research Center of the ADA Health Foundation,  
National Institute of Standards and Technology, Department of Commerce, Gaithersburg,  
MD

Dr. William Maas, Director, Division of Oral Health, Centers for Disease Control and Prevention,  
Chamblee, GA

## OPEN PORTION OF THE MEETING

### I. CALL TO ORDER

Dr. Lawrence A. Tabak, Director, NIDCR, called the meeting to order. He asked for a moment of silence in remembrance of the seven astronauts lost in the space shuttle Columbia's disaster on February 1. He then invited all attendees to introduce themselves.

### II. APPROVAL OF MINUTES

The minutes of the Council's meeting on September 27, 2002, were considered and unanimously approved.

### III. OPERATING PROCEDURES

The Council unanimously concurred with the rules governing the Council's operating procedures.

### IV. FUTURE COUNCIL MEETING DATES

The following dates for future Council meetings were confirmed:

June 16, 2003  
September 19, 2003

January 20, 2004  
May 25, 2004  
September 28, 2004

### V. REPORT OF THE DIRECTOR

Dr. Tabak highlighted several items from the written Director's Report (see Attachment III).

**Outreach.** Dr. Tabak noted that, over the past few months, he continued to visit dental schools and organizations to promote collaborative research efforts and to discuss future directions in dental, oral, and craniofacial research.

***Activities of the NIDCR Deputy Director.*** Dr. Tabak noted that Dr. Dushanka V. Kleinman, Deputy Director, NIDCR, met with Chief Dental Officers from other countries at the annual meeting of the Fédération Dentaire Internationale and briefed Surgeon General Richard Carmona on national issues facing dentistry and oral health. Dr. Kleinman commented that the development of the National Oral Health Call to Action is well underway and that NIDCR anticipates distributing the final, published document to Council at its June 2003 meeting. The document, which is a follow-up to *Oral Health in America: A Report of the Surgeon General*, will be issued by the Department of Health and Human Services and the Partnership Network. Dr. Caswell Evans is the NIDCR lead in this effort.

***NIH Activities.*** Dr. Tabak reported that the NIH extramural loan repayment programs (LRPs) for clinical and pediatric research have been extended to non-NIH grantees. At NIDCR, Dr. James Lipton, Ms. Lorraine Jackson, and Dr. Sharon Gordon, who are responsible for NIDCR training and career development activities (see below), can answer questions about these programs. Dr. Tabak said that NIDCR has begun to develop its FY 2005 scientific initiatives and is seeking input and advice broadly from the dental, oral, and craniofacial research community. Dr. Tabak also noted that, on November 14, he testified on behalf of NIH and NIDCR at a hearing on ongoing scientific research related to dental amalgam. The hearing was convened by Representative Dan Burton (R-IN), former Chair of the House Committee on Government Reform. Participating in one of two panels, Dr. Tabak discussed the two clinical trials funded by NIH which are comparing the health of more than 1,000 children exposed to elemental mercury in dental amalgams. To date, neither trial has shown any harmful effects attributable to amalgam.

***Meetings and Workshops.*** Dr. Kleinman said that the first national conference on dentistry's role in bioterrorism and other catastrophic events will be held in Washington, DC, March 27-28, 2003. She noted that the emergence of these concerns affects all of dentistry—dental education, practice, and research—and dentistry's role as a profession. Dr. Kleinman named some of the speakers and encouraged the members of Council and the attendees at the Council meeting to register and attend the conference.

Recently, NIDCR hosted the first meeting of NIDCR grantees who are contributing to NIDCR's initiative to develop novel technologies using saliva as a diagnostic tool. Dr. Tabak said that the exchange of ideas at the meeting was very exciting and that NIDCR looks forward to the investigators' progress. Dr. Eleni Kousvelari, Chief, Cellular and Molecular Biology, Physiology, and Biotechnology Branch, Division of Basic and Translational Sciences (DBTS), directs this NIDCR program.

***NIDCR Training and Career Development.*** Dr. Tabak said that NIDCR has centralized its training and career development activities within the Office of the Director (OD), NIDCR. This "virtual office" will integrate NIDCR's extramural and intramural activities in training, career development, dental school infrastructure, and outreach and recruitment. Dr. Kleinman will head this unit. Within the group, Dr. James Lipton will direct the dental school research infrastructure and curriculum development program. Dr. Tabak noted that Dr. Lipton has provided long and stellar leadership for the NIDCR extramural training and career development program and, together with the Council, applauded his efforts. Dr. Tabak said that Dr. Sharon Gordon has been highly

successful in coordinating training activities in the NIDCR Division of Intramural Research and will now oversee both intramural and extramural training and career development. Noting that Ms. Lorraine Jackson is a “recruiter extraordinaire,” Dr. Tabak said that she will lead extramural recruitment and outreach activities.

**NIH Center for Scientific Review (CSR).** Dr. Tabak said that the ongoing reorganization of CSR will continue over the next 2 years and is a “work in progress.” Drs. Kleinman and Kousvelari serve as the NIDCR representatives in this process. The status of reorganization activities is posted on CSR’s Web site (<http://www.csr.nih.gov/review>). Dr. Tabak encouraged the Council members to provide input and feedback on the reorganization as it proceeds. In the CSR reorganization, the Oral Biology & Medicine study sections (OMB-1 and OMB-2) are included in a new Integrated Review Group (IRG) on Musculoskeletal, Oral, and Skin Sciences. The plan is to launch the new IRG and its study sections at the October–November 2003 review of applications received by June 1, 2003. Dr. Tabak noted that a tentative posting of OMB study section members is scheduled for April 2003 and that CSR will be asking current study section members to indicate before April which study section they prefer to be in. With the reorganization, most applications formerly reviewed by OMB-1 will be reviewed by a new Oral, Dental, and Craniofacial Sciences (ODCS) study section; applications in oral cancer research will be reviewed by a Cancer study section; applications in developmental biology, as well as genetics, research will be reviewed by the ODCS study section; and applications in biomineralization research will be reviewed by a new Skeletal Biology and Development and Disease study section.

**NIDCR Personnel.** Dr. Tabak noted that the Grants Management Branch, Division of Extramural Activities, has three new staff members: Ms. Mary Daley, grants management officer, and Mr. Christopher Myers and Ms. Diana Rutberg, grants management specialists. Additional appointments were noted by the NIDCR divisions and branches during their reports in the closed session.

Additional information on these and other NIDCR activities is provided in the written Director's Report (Attachment III).

## VI. CONCEPT CLEARANCES

Dr. Tabak noted that development and presentation of concept clearances for the Council’s review are in the earliest planning stages for NIH initiatives and may result in a Request for Applications (RFA), Request for Proposals (RFP), or program announcement. The initiatives are one vehicle for “showcasing” an institute or center’s (IC’s) research goals and future program directions.

Dr. Tabak emphasized that concepts approved by the Council may or may not result in RFAs, RFPs, or program announcements, which depend on the availability of funds.

Dr. J. Ricardo Martinez, Executive Secretary, NADCRC, and Associate Director for Program Development, OD, reminded the Council of his report, at the previous Council meeting, on the status of concept clearances approved by the Council during Fiscal Year (FY) 2002. He introduced staff from OD, the Division of Population and Health Promotion Sciences (DPHPS), and DBTS who presented the following six new concepts for review.

### Clinical Trial of Topical Thalidomide for Aphthous Stomatitis in Patients with HIV/AIDS

Dr. Sharon Gordon presented a concept for an RFP to assess the efficacy and safety of a novel topical thalidomide formulation for healing of aphthous ulcers associated with HIV/AIDS. Recurrent aphthous ulcers are a frequent oral manifestation in HIV-infected patients, causing substantial morbidity, such as oral pain which leads to decreased food intake and increased weight loss, as well as diminished quality of life. There are no satisfactory therapies or accepted standards of care for aphthous ulceration in HIV-seropositive (+) patients. Various interventions are available for aphthous ulcers, but these have been variably successful and most have not been tested in HIV-infected patients, the group that suffers the most from aphthous ulcers. Thalidomide, administered orally, is effective for aphthous ulcers in HIV+, as well as immunocompetent patients, but its use is limited by the spectrum of adverse effects. Alternative treatment strategies are needed. Topical administration of the drug is a strategy that could enhance absorption at the target site while lowering drug concentrations in the plasma and, hence, decreasing the potential for toxicity. A pilot clinical trial demonstrated that 20 mg of thalidomide administered topically effectively promoted healing and reduced pain for a mean of 17 days, with minimal systemic absorption and adverse effects. The proposed multicenter clinical trial would test the efficacy of topical thalidomide for lesion healing and diminution of pain, as well as toxicity, in patients with aphthous ulcers associated with HIV/AIDS.

The Council unanimously approved the concept.

### Molecular Anatomy of Head and Neck Cancer: A Genomic/Proteomic Approach

Dr. Yasaman Shirazi, Health Scientist Administrator and Program Director, Epithelial Cell Regulation and Transformation Program, DBTS, presented a concept for an RFA to encourage basic and translational research to decipher the complex molecular networks involved in the development of head and neck squamous cell carcinomas (HNSCCs). These cancers, which affect the oral cavity, salivary glands, larynx, and pharynx, are the sixth most common cancer in the developed world and are often associated with low survival and high morbidity rates. The high mortality rates may be due, in part, to HNSCCs being usually diagnosed at later stages of disease. Thus, early diagnosis is a key factor in slowing the progression of these cancers and improving the patients' response to treatment and, ultimately, quality of life and survival. The recent sequencing and annotation of the human genome and the development of highly sensitive, high-throughput techniques offer a unique opportunity for scientists to comprehensively characterize the molecular aspects of normal, precancerous, and malignant cells. By utilizing these techniques in combination with novel and emerging proteomic technologies, scientists may be able to unravel the nature of the molecular alterations in HNSCCs. The proposed initiative would foster collaborative and multidisciplinary research using state-of-the-art genomic and proteomic approaches to focus on (a) correlation of the genomic state, gene transcription profiles, and protein expression and activity with the functional status of normal and aberrant cells, and (b) development of novel biomarkers for early detection of pre-neoplastic and neoplastic lesions, which could also serve as targets for therapy.

The Council unanimously approved the concept.



## Clinical Genetics of Craniofacial and Oral Disorders

Dr. Rochelle Small, Health Scientist Administrator and Program Director, Developmental Biology and Mammalian Genetics Program, DBTS, presented two complementary concepts related to clinical research on craniofacial and oral disorders (see also the next concept below). One concept is for an RFA for clinical genetics research on the genes and environmental factors that cause or modify susceptibility to craniofacial, oral, and dental disorders and diseases. As noted above, an array of new and emerging genomic and proteomic tools and approaches are available and can be combined to facilitate progress in clinical genetics studies. For craniofacial disorders, however, several obstacles must be overcome to take advantage of these new capabilities and to accelerate research progress. Major hindrances are the phenotypic variation currently found in individuals with the same craniofacial disorder and the lack of clinical consensus on phenotypic definitions of the various disorders and diseases. The primary goal of the proposed initiative is to develop well-characterized populations of patients with specific craniofacial disorders. The initiative would foster unique partnerships between clinicians and basic scientists to refine clinical phenotypic characterizations, develop rigorous diagnostic criteria based on standardized and comprehensive phenotypic definitions, define the natural history of craniofacial disorders, and identify diagnostic biomarkers. The initiative would support clinical research to accrue patient populations with these disorders for accurate and comprehensive clinical, genetic, molecular, and biochemical assessment.

The Council unanimously approved the concept.

## Research Registries and Repository for Oral and Craniofacial Genetic Disorders

Dr. Rochelle Small presented a second, related concept to stimulate and facilitate research on oral and craniofacial genetic disorders. This concept is for an RFP to establish (a) one or more research registries for families with these disorders in the United States and abroad; (b) uniformly accepted clinical diagnostic criteria that provide a detailed characterization of the phenotype of these disorders, including variations; and (c) a repository that will collect genomic samples (i.e., DNA, RNA) and affected tissue samples from patients with these disorders, for generating cell lines and distributing DNA and cell lines to researchers in the United States and abroad. The registries and repository would serve as a national and international resource and would stimulate and facilitate national and international collaborative research, including basic studies, gene discovery, epidemiology, and clinical trials for genetic disorders affecting craniofacial, oral, and dental tissues. They would facilitate standardized protocols for collecting and storing tissue samples and patients' data; management of tissue and data records in a comprehensive, computerized database; sharing of data and research collaborations; provision of information on the prevalence of disorders; genetic studies; and links to related databases. The registries and repository would be coordinated with similar efforts supported by other Federal agencies.

The Council unanimously approved the concept.

## The Genomics and Proteomics of Periodontal Diseases

Dr. Dennis F. Mangan, Chief, Infectious Diseases and Immunity Branch, DBTS, presented a concept for an RFA that would stimulate research that utilizes contemporary, high-throughput technology and bioinformatics to identify and characterize genes and proteins associated with periodontal diseases and health. Studies would focus on functional aspects and both host and microbial responses and would establish a scientific basis for identifying logical targets for preventing, diagnosing, and treating periodontal diseases. Periodontal diseases are a significant public health burden in the United States, as well as worldwide, and total expenditures for treatment and preventive procedures in the United States in 1999 amounted to \$14.3 billion. Some form of periodontal disease (including gingivitis) affects an estimated 85 percent of the U.S. adult population, with severe periodontal disease affecting an estimated 12 percent to 15 percent. This burden can be expected to increase as the U.S. population ages. Genomics and proteomics offer a new “gateway” to understand the etiology and pathogenesis of periodontal diseases. During the past 5 years, researchers have taken advantage of these advanced genetic techniques to identify hundreds of new species of oral bacteria, and they now have a more complete appreciation of the importance and complexity of microbial biofilms, the immune responses involved in chronic inflammation, the molecular basis of alveolar bone loss, and the biology of accelerated tissue regeneration. The time is ripe for combining this genetic understanding with data emerging from the study of proteins in a comprehensive approach to determine the role of all genes and proteins in the pathogenesis and virulence of periodontal diseases. This initiative would encourage increased research in these areas and would emphasize the use of bioinformatics technology to collate the data generated and to make the data available to all researchers.

In discussion, the Council suggested that NIDCR consider two modifications, to: (i) revise the title of the proposed concept to indicate NIDCR’s interest in research on both the genetic host and microbiological aspects of the human predisposition to periodontal diseases, and (ii) include wording to encourage investigators to address the implications of their research findings to prevention, diagnosis, and treatment of these diseases.

The Council unanimously approved the concept.

## Oral Mucosa and HIV Infection

Dr. Mangan also presented a concept for an RFA to examine the structure, biology, genetics, physiology, and biochemistry of the oral mucosa and to compare these features with other mucosal surfaces, especially vaginal and rectal mucosa, in regard to susceptibility or resistance to HIV infection and replication. Studies in animals indicate that the HIV can enter via the oral mucosa, yet epidemiology studies indicate that the relative risk of adults becoming infected with this virus through the oral route is relatively low. In a few studies, the HIV provirus has been found in the epithelial tissues of HIV-infected individuals, but evidence of a productive infection is limited. There is evidence to suggest that the oral mucosa resists, and may prevent, HIV infection despite harboring HIV. This evidence contrasts with that for other viruses, such as Epstein-Barr virus or human papillomavirus, which can infect the oral mucosa. Oral epithelial cells are rich sources of microbicidal agents and innate host immune factors. The oral mucosal surface is highly amenable to research, yet few studies are examining the importance of these tissues in the potential prevention

of HIV infection and AIDS-related oral manifestations. More research is needed to better understand the uniqueness of the oral mucosa, particularly in comparison with vaginal and rectal mucosa. The proposed initiative would stimulate additional research to define the immunological, genetic, physiological, and biochemical aspects of the oral epithelium that confer susceptibility or resistance to HIV infections. This research effort would be coordinated with NIDCR-supported research on the immunological properties of saliva.

The Council unanimously approved the concept.

## VII. REVIEW OF NIDCR IMPLEMENTATION OF NIH POLICY ON INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

Dr. Richard L. Mowery, Chief, Clinical, Epidemiology and Behavioral Research Branch, DPHPS, presented in brief, for Council's approval, a report documenting NIDCR's activities over the past 2 years to ensure that women and minorities are included as subjects in clinical research. As stipulated by the NIH Revitalization Act of 1993, the advisory councils of each IC must prepare a biennial report describing the activities of IC staff to comply with the Act, as well as results of these activities as reflected in enrollment statistics. The report was mailed to all Council members for their review prior to the meeting.

The Council's report is presented in two major sections: NIDCR training and outreach activities, and NIDCR procedures for tracking and monitoring inclusion of women and minorities. Dr. Mowery noted that, during the past 2 years, NIDCR extramural and grants management staff have participated in NIH training courses and NIDCR program directors have assisted extramural investigators whose applications involve human subjects, to ensure that they address inclusion of women and minorities. In addition, program directors have ensured that any concerns raised during the peer review of applications were adequately addressed by applicants and that target enrollments were reported and entered into the central NIH tracking database. Additional details on these and related activities are included in the Council's report.

The report also includes a table showing the aggregate enrollment data by population group for NIDCR-supported extramural research protocols funded in FY 1999 and FY 2000, as required by the Act. Dr. Mowery noted that the FY 2000 NIDCR data are consistent with the aggregate enrollment data reported for the NIH.

The Council approved the report and concurred with its submission to the Congress.

## VIII. BUDGET

Dr. Tabak presented an overview of the NIDCR budgets for FY 2002, 2003, and 2004. A handout of the slides was provided to the Council.

## FY 2002

The total NIDCR budget was \$342,293,000 in FY 2002. Most of the funds (\$264,909,000) were allocated to extramural activities; the remainder was divided between intramural research (\$57,796,000) and research management and support (\$19,588,000). Elaborating on the total funding for intramural research, Dr. Tabak noted that this category included support for central assessments (made across NIH), assessments for NIH facility needs, and renovation of NIDCR laboratories, as well as intramural research activities within the Division of Intramural Research—which accounted for about \$33.5 million of the total \$57.8 million allocated for intramural research.

The extramural budget for FY 2002 was distributed across the following award mechanisms: research projects (for a total of 615 noncompeting and competing projects), Small Business Innovation Research (SBIR) and Small Technology Transfer Research (STTR) awards (28), research centers, research careers, other research related, research training, and research and development (R&D) contracts. NIDCR supported a total of 760 extramural research grants, with a pay line of 24 percent and a success rate of 29.3 percent—which is comparable to the 31.3 percent success rate for the NIH. NIDCR funded seven new training awards (T32s) under the National Research Service Award program and 19 career development awards (K22s). The percentage distribution is as follows: research project grants (76 percent), centers (9 percent), contracts (7 percent), training (3 percent), and other (5 percent).

Dr. Tabak noted that 78 percent of NIDCR's budget was already committed (for grants, contracts, and mandatory increases for direct-operating expenditures at NIH) during FY 2002 and that 22 percent of the budget was discretionary funding available for new activities. For competing research project grants, 70 percent of the funds were already committed (commitments of record) and only 30 percent was available for new, competing awards. Dr. Tabak also noted that approximately \$27.2 million was allocated for various taps and assessments ("the price of doing business"), most of which (\$17.3 million) was for the NIH management fund and rent. Dr. Tabak commented that these fiscal realities led NIDCR to continue its moratorium on funding of new program project grants (PO1s) and to reduce the award amounts for competing grants up to 8 percent from recommended levels, except for new investigators.

Within the budget available for FY 2002, NIDCR emphasized three areas of initiatives: increased clinical research, bioengineering, and HIV/AIDS research. Dr. Tabak commented that the Institute's portfolio of clinical research grants increased by 22 percent over FY 2001, represented 30 percent of the research and training budget, and included a 25 percent increase in the number of clinical trials supported. The expanded clinical research activity includes Obstetrics and Periodontal Therapy (OPT) Clinical Trials, Specialized Programs of Research Excellence (SPORE), the Temporomandibular Joint Disorders (TMJD) Registry, pilot and planning grants for research on health disparities among minority populations, and funding of the first set of Minority Dental School Infrastructure grants. Among the robust set of initiatives supported in tissue repair and regeneration and biomaterials, NIDCR funded two key initiatives in FY 2002: Stem Cells in Development/Repair of Orofacial Structures, and Development of Technologies for Saliva/Oral Fluid-Based Diagnostics. In HIV/AIDS research, NIDCR supported exploratory AIDS-related research and studies of the oral transmission of HIV.

## FY 2003

Dr. Tabak noted that NIDCR is still operating under a Government-wide continuing resolution for FY 2003. Nonetheless, NIDCR has been able to increase clinical research; capitalize on advances in bioengineering, genomics, and proteomics; and stimulate HIV/AIDS research. Specific initiatives in clinical research relate to TMJDs, the planning for and piloting of clinical trials, international research registries for Sjögren's syndrome, and the dental school infrastructure program and dental school curriculum development. Three initiatives in basic research relate to biomimetics, novel genes involved in craniofacial disorders, and biofilms. Two initiatives in HIV/AIDS research relate to innate mucosal factors and oral mucosal vaccination against HIV infection and HIV-related opportunistic pathogens.

Dr. Tabak stated that, for the future, NIDCR plans to take advantage of the wealth of data and research opportunities emerging from the continued development of state-of-the-art technologies and advances in human genomics and proteomics. Some of the exciting, new initiatives being planned were presented as concept clearances earlier during the meeting (see section VI above). Additional, planned initiatives relate to the modeling of complex diseases such as Sjögren's syndrome, use of a genomics/proteomics approach to understand the molecular anatomy of pain, and AIDS-related oral malignancies and tumors and AIDS-related research in special populations.

## FY 2004

Dr. Tabak noted that NIDCR's budget for FY 2004 will be based on the final budget for FY 2003. NIDCR's budget request for FY 2004 is \$382.4 million. For FY 2003, NIDCR requested a budget of \$370.4 million and is currently operating on an amended budget of \$369.3 million. The budget requested for FY 2004 reflects a \$13.1 million increase, or about 3.5 percent, over the amended budget. The budget requested would sustain an estimated success rate of 25 percent for competing research project grants, support for three phase II dental school infrastructure awards, and an increase of up to 4 percent in stipends for research trainees. Dr. Tabak noted that total support for extramural activities would, for the first time, be more than \$300 million and that NIDCR aims to ensure that the success rate can be maintained as high as possible.

Three research initiatives highlighted for FY 2004 are: Molecular Anatomy of Head and Neck Cancer: A Genomic/Proteomic Approach; Genomics of Craniofacial and Oral Disorders; and Topical Thalidomide for Oral Lesions of HIV/AIDS (see section VI above for a description of the concepts for these initiatives). NIDCR also would highlight the phase II dental school infrastructure initiative.

Dr. Tabak added that the FY 2004 budget request for all of NIH reflects an increase of \$549 million for NIH. He noted that this budget would increase the overall NIH investment in research by 7.5 percent (excluding buildings and facilities), with an increase of 4.3 percent for non-biodefense research.

## Discussion

The Council commented on the importance of intramural research, the NIDCR budget, clinical research, dental school infrastructure, patient advocacy, and evaluation research. Two other topics also were mentioned.

***Intramural Research.*** Dr. Tabak stated that intramural research tends to account for approximately 10 percent of the total NIDCR budget and that it remains crucially important. He noted that, although the percentage of funds allocated to intramural research has decreased gradually over time, this in-house research is a very wise investment of NIDCR's resources, offering "incredible science" and excellent training opportunities. He also noted that Congress most immediately associates NIH with intramural research and that NIH needs to maintain a robust and vigorous intramural program. The Council commented especially on the value of postdoctoral training at NIH.

***NIDCR Budget.*** The Council urged continued advocacy for NIDCR's FY 2003 budget request, as a base on which to build the FY 2004 budget. The Council congratulated NIDCR on maintaining low (5–7 percent) administrative costs, which staff noted are comparable across the NIH.

***Clinical Research.*** The Council agreed with and complimented NIDCR on its focus on clinical research. Dr. Tabak thanked the Council for its advice, leadership, and support of this Institute emphasis. He said that, with Council's advice and depending on the availability of funds, NIDCR may be able to preferentially apply new monies or may have to shift existing uncommitted resources to enhance the clinical research portfolio. He noted that support of any program or project reflects three priority criteria: scientific opportunity, feasibility and potential impact on public health, and alignment with NIDCR goals. Dr. Tabak emphasized that basic science and clinical research are complementary efforts in a "push–pull" dynamic whereby each endeavor stimulates the "bubbling up" of research ideas and opportunities.

Noting that NIDCR's involvement in large clinical trials is relatively new, the Council encouraged the Institute to seek collaborations with other ICs to fund NIDCR-initiated clinical trials. Dr. Tabak stated that NIDCR seeks and welcomes partnerships. He noted that equal partnerships are most effective and that, to gain these, NIDCR must not waive in its resolve, must focus research on the most promising ideas, and must demonstrate its steadfastness to the dental community and the broader NIH research community. He noted further that NIDCR has made investments in infrastructure (e.g., registries, dental school research and curriculum development) to support expansion of clinical trials.

The Council encouraged NIDCR to "stay the course" in emphasizing clinical research, noting that NIDCR-supported research may be the "economic engine" that will stimulate partnerships between industry and universities on research ideas with commercial potential. The Council asked about the possibility of NIDCR serving as a data management and coordinating center for clinical trials, to reduce the costs of clinical trials and to maintain high-quality data management. Staff noted that the issue of establishing database management centers at the NIH versus extramurally has been discussed widely and that maintaining these facilities in the extramural research community is considered a better option, for scientific, efficacy, and budgetary reasons.

The Council encouraged NIDCR to partner with community-based organizations and to provide resources to stimulate their involvement and enhance the participation of underrepresented and underserved populations in clinical research. Dr. Tabak commented that enhancing the inclusion of these populations in clinical research is a challenge across the NIH and that NIDCR staff are addressing this concern.

***Dental School Infrastructure.*** The Council emphasized the need to continue to strengthen dental research within dental schools. The Council commended NIDCR on the new dental school infrastructure program and its long history of supporting infrastructure in dental schools. As part of NIDCR's outreach, the Council encouraged NIDCR to advise dental schools about the availability of the Council's minutes on the NIDCR Web site (<http://www.nidcr.nih.gov>) and the availability of the minutes of meetings of dental professional organizations.

***Patient Advocacy.*** The Council congratulated NIDCR for its pioneering emphasis on and promotion of patient advocacy. The Council noted that the Patient Advocacy Forum is an important resource for NIDCR, for establishing and promoting registries and databases and for disseminating research findings to patients and the public.

***Evaluation Research.*** The Council noted that evaluation is an integral part of NIDCR activities and that one of NIDCR's main contributions for the future will be its evidence-based prioritization of research directions. Dr. Tabak commented that NIDCR has developed an evaluation plan for its health disparities research initiative and is working to include evaluation in its large research projects from the beginning. He noted that these prospective evaluations, combined with NIDCR's ongoing retrospective evaluations which have been conducted for smaller programs for many years, the day-to-day program evaluations conducted by staff, and special evaluations from time to time will yield an important set of data for making program determinations. Following the present Council meeting, a working group of the Council met to discuss NIDCR's evaluation activities.

***Other Topics.*** In response to a question about NIDCR's contribution to an Institute of Medicine study on increasing the diversity in academic health centers, Dr. Kleinman commented that NIDCR continues to participate in the broader, ongoing National Academy of Sciences' study of biomedical and behavioral research personnel. NIDCR is pursuing inclusion of an oral health component in the broader study.

The Council commented on the selection of study section members, expressing deep concern that politics has become a measure in the selection process.

#### CLOSED PORTION OF THE MEETING

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

There was a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

## IX. REVIEW OF APPLICATIONS

### Grant Review

The Council considered 386 applications requesting \$75,205,782 in total costs. The Council recommended 315 applications for a total cost of \$62,899,244 (see Attachment II).

### ADJOURNMENT

The meeting was adjourned at 2:45 p.m. on February 3, 2003.

### CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

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Dr. Lawrence A. Tabak  
Chairperson  
National Advisory Dental and  
Craniofacial Research Council

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Dr. J. Ricardo Martinez  
Executive Secretary  
National Advisory Dental and  
and Craniofacial Research Council

## ATTACHMENTS

- I. Roster of Council Members
- II. Table of Council Actions
- III. Director's Report to the NADCRC, February 2003

NOTE: A complete set of open-portion handouts is available  
from the Executive Secretary.